COOLEY GODWARD LLP
STEPHEN P. SWINTON (106398)
JAMES DONATO (146140)
4365 Executive Drive, Suite 1100
San Diego, CA 92121-2128
Telephone: (858) 550-6000
Facsimile: (858) 453-3555

Attorneys for Plaintiff
Gen-Probe Incorporated

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. 99CV2668H AJB

FIRST AMENDED COMPLAINT FOR DECLARATORY RELIEF AND UNFAIR COMPETITION

PLAINTIFF GEN-PROBE ALLEGES:

INTRODUCTION

1. This action concerns the nature and scope of any obligation of plaintiff Gen-Probe Incorporated ("Gen-Probe") to make royalty payments to defendant Vysis, Inc. ("Vysis") pursuant to a patent license agreement between the parties ("the License") in light of the invalidity and non-infringement of United States Patent No. 5,750,338 ("the '338 patent") that is a subject of that License. As set forth below, Gen-Probe asks this court to declare the '338 patent invalid and further to declare that Gen-Probe's current and anticipated activities do not infringe any valid claims of the '338 patent. As a corollary to those declarations, Gen-Probe also asks this Court to declare its rights and obligations under the terms of the parties' License. Finally, Gen-Probe also seeks relief from Vysis' continuing acts of wrongful and unfair conduct with respect to the '338 patent.

THE PARTIES

2. Gen-Probe was founded in San Diego in 1984 as a small "start up" company, seeking to develop products based on the discoveries of a local research scientist. Over time, Gen-Probe became one of the largest biotechnology firms in San Diego. Gen-Probe now maintains its principal offices and research facilities at 10210 Genetic Center Drive in San Diego, where it employs over 500 scientists and staff. Gen-Probe is organized under the laws of the State of Delaware.

3. Gen-Probe is informed and believes that defendant Vysis, Inc. (hereinafter "Vysis" or "the defendant") is a corporation organized and incorporated under the laws of the State of Delaware. Gen-Probe is further informed and believes that Vysis maintains its principal place of business in Downers Grove, Illinois and that it is controlled by BP Amoco, Inc.

JURISDICTION AND VENUE

4. Counts One and Two of this Complaint seek declaratory relief under the Declaratory Judgment Act, Title 28, United States Code, Sections 2201 and 2202. This Court has subject matter jurisdiction of the claims asserted thereunder by reason of Title 28, United States Code, Sections 1331, 1338(a), 1338(b) and 1367.

5. Venue is proper in this District under Title 28, United States Code, Sections 1391(b) and 1400(b).

BACKGROUND

6. Living cells store genetic information in molecules of nucleic acid known as DNA. These molecules consist of long, thin, chain-like strands which, in turn, are usually found in the form of two tightly bound, complementary chains. DNA molecules retain their genetic information in the form of a genetic code. The information in the DNA determines the life processes of each organism. The information in the DNA is used to make related nucleic acid molecules called RNA that cells use to manufacture proteins.

7. Through the work of its scientists and staff, Gen-Probe has developed and continues to develop diagnostic tests that seek out the DNA or RNA of the infectious organisms. These types of tests are generally referred to as "genetic probes" or "nucleic acid tests" ("NAT"). Gen-Probe

now markets DNA probe products that test for a wide range of microorganisms that cause tuberculosis, strep throat, pneumonia, fungal infections and sexually transmitted diseases. Through the efforts of its scientists and staff, Gen-Probe has emerged as the recognized world leader in the development, manufacture and commercialization of diagnostic products based on its patented genetic probe technology. Gen-Probe has received over 40 FDA clearances and approvals for genetic probe tests to detect a wide range of microorganisms, including Chlamydia trachomatis, Mycobacterium tuberculosis and Neisseria gonorrhoeae.

8. Many human diseases are caused by bacterial or viral agents that invade living cells. Historically, the presence of these bacterial or viral agents was detected directly by time-consuming methods such as culture or indirectly through the detection of antibodies. Unfortunately, it takes time, sometimes weeks or months, to grow organisms in culture, and it usually takes months for the body to manufacture antibodies in sufficient amounts to reveal the presence of infectious agents. Consequently, these methods do not lend themselves to early detection of infection. NAT addresses this problem.

9. Among the disease detection technologies recently applied by Gen-Probe is its patented nucleic acid technology known as "Transcription-Mediated Amplification" ("TMA"). This technology enables Gen-Probe's NAT products to detect extraordinarily small quantities of the nucleic acids of infectious agents.

10. In September 1996, Gen-Probe received a $7.7 million grant from the National Institutes of Health to develop TMA-based nucleic acid tests to be used in screening donated blood for and human immunodeficiency virus (HIV), the causative agent of AIDS, and hepatitis C virus (HCV), which causes a severe form of hepatitis.

11. At the time of the NIH grant to Gen-Probe, donated blood was principally tested by procedures that detected the presence of antibodies to the viruses being screened. Due to the time it takes for the body to make antibodies after initial infection, donated blood may test negative for antibodies, yet still carry infectious viruses. This delay between the time of actual infection and the time that antibodies can first be detected is often known as the "window period." Reduction of this "window period" was a significant concern of the United States government and the primary focus

of the grant to Gen-Probe to develop NAT diagnostics for use in blood screening.

12. In fulfilling its obligations under the grant, Gen-Probe developed NAT tests to detect the DNA of HIV and hepatitis C in blood. Through the use of its NAT test, Gen-Probe believes that researchers and medical personnel may rapidly and *directly* detect the presence of genetic material of viruses like HIV and HCV more accurately and without the complications and delay associated with conventional *indirect* tests. As such, Gen-Probe believes that its new test may significantly reduce the "window period" for detection of these extremely harmful viral agents and resulting diseases.

13. Final development of the NAT tests for blood screening in the United States is now taking place in testing conducted by the American Red Cross, America's Blood Centers, and others. ("A Purity Quest; Local Biotech's Ultra-Sensitive Blood Screening Could Cut Risk of AIDS, Hepatitis," *San Diego Union*, March 25, 1999, page C-1.) Use of the tests in the United States is made pursuant to an Investigational New Drug Application filed with the United States Food and Drug Administration. In blood tested by the American Red Cross, Gen-Probe's products have detected hepatitis C and HIV which escaped detection by prior methods. ("New Blood Screening Finds Virus Others Missed; Experimental Test Turns Up Hepatitis C In Donated Blood," *San Diego Union*, April 2, 1999, page B-2.)

14. On September 21, 1999, the French Ministry of Health approved the sale of the Gen-Probe blood screening tests in France. Gen-Probe anticipates approval of its tests for us in Australia in early 2000.

15. Gen-Probe has entered into an agreement with Chiron Corporation ("Chiron") of Emeryville, California, with respect to the development, manufacture, and distribution of blood screening products. Gen-Probe is also a party to an agreement with Bayer Corporation ("Bayer") of Emeryville, California with respect to the development, manufacture, and distribution of clinical diagnostic products for the detection of HIV and hepatitis C, among other pathogens.

16. Gen-Probe anticipates that additional clinical trials in the United States of its HIV/HCV tests for use in blood screening and in clinical diagnostics will commence in the first part of 2000. Gen-Probe anticipates the conclusion of those clinical trials, and the initiation of

commercial sales in the United States of kits containing its HIV/HCV blood screening test, during 2000.

17. All of the Gen-Probe products are manufactured in San Diego, California.

THE '338 PATENT

18. Gen-Probe is informed and believes that on or about May 12, 1998, the United States Patent and Trademark Office issued United States Patent No. 5,750,338 ("the '338 patent") based upon Patent Application No. 238,080 filed on May 3, 1994.

19. Gen-Probe is informed and believes that defendant Vysis claims to be the owner, by assignment, of the entire right, title and interest of the '338 patent. The claims of the '338 patent purport to relate to assays and probes for polynucleotide molecules such as DNA and RNA.

20. In early 1999, Vysis informed Gen-Probe that it believed that the '338 patent "applied" to Gen-Probe's NAT blood screening tests for HIV and HCV. Following further discussions and to avoid any complications in Gen-Probe's plans for commercial deployment of its NAT test kits, as of June 22, 1999 Gen-Probe obtained a license ("the License") from Vysis under the '338 patent. Gen-Probe also obtained options to the License for its relationships with Chiron and Bayer.

21. Under the terms of the License, Vysis requires Gen-Probe (and its allied parties if the options are exercised) to make significant financial payments to Vysis as royalties on the sale of any product covered by any valid claims of the '338 patent.

22. Notwithstanding the existence of the License, and as further alleged herein, Gen-Probe believes that the claims of '338 patent are invalid in all material respects. Furthermore, Gen-Probe believes that its NAT blood screening tests do not infringe any valid claim of the '338 patent. As such, Gen-Probe disagrees with Vysis' contention that the claims of the '338 patent "apply" to Gen-Probe's activities and contemplated products. For these same reasons, Gen-Probe contends that it has no obligation to make any royalty payments to Vysis with respect to its present products and activities and any contemplated products and activities that Vysis may later claim infringe the claims of the '338 patent.

23. Gen-Probe has communicated to Vysis its belief that the claims of the '338 patent

are invalid. In support of that belief, Gen-Probe has provided Vysis with information that demonstrates that the claims of the '338 patent are invalid. Gen-Probe has also advised Vysis of its belief that its NAT test kits for use in detecting HCV and HIV in the Nation's blood supply do not and will not infringe any valid claims of the '338 patent.

24. Notwithstanding its receipt of the foregoing information, Vysis persists in its assertion that the claims of the '338 patent are valid and enforceable and that Gen-Probe is obligated to make royalty payments in accordance with the terms of the License.

25. Based upon a long history of litigation between Gen-Probe and Vysis and its affiliates, Gen-Probe reasonably anticipates that should it fail to pay royalties pursuant to the License, Vysis will aggressively attempt to enforce its perceived rights under both the License and the '338 patent by terminating the License and by initiating litigation against Gen-Probe, its allied parties, and customers.

26. An actual case or controversy exists between Gen-Probe and Vysis concerning the validity and infringement of the '338 patent and Gen-Probe's rights and obligations under the License. The determination of the issues presented in this complaint will inure to the greater public benefit and good.

COUNT ONE

NON-INFRINGEMENT OF THE '338 PATENT

27. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

28. Gen-Probe's NAT test kits for use in detecting HCV and HIV in the Nation's blood supply do not and will not infringe any valid claims of the '338 patent.

COUNT TWO

INVALIDITY OF THE '338 PATENT

29. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

30. The claims of the '338 patent are invalid by reason of one or more provisions of Title 35 of the United States Code.

COUNT THREE

DECLARATORY RELIEF

31. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

32. An actual controversy has arisen and now exists concerning the rights and obligations of Gen-Probe pursuant to the terms of the parties' License. Those disputes arise from and their resolution depends upon the federal patent laws.

33. Gen-Probe seeks a declaration of its rights and obligations under the License, particularly in light of the invalidity and non-infringement of the '338 patent and defendant's acts of unfair competition as alleged herein.

COUNT FOUR

UNFAIR COMPETITION

34. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 33 of this complaint.

35. Vysis knows or should know the underlying facts establishing the invalidity of the claims of the '338 patent. In continuing to enforce the claims of the '338 patent, Vysis has acted and continues to act unfairly, inequitably and in bad faith. In addition, Vysis' actions constitute unlawful, unfair or fraudulent business practices under California Business & Professions Code Sections 17200, *et seq.*

36. By reason of the aforementioned acts of unfair competition and unlawful, unfair and fraudulent business practices, Gen-Probe is entitled to damages, as established at time of trial, restitution and injunctive relief.

WHEREFORE, Gen-Probe prays as follows:

1. For declarations:

a. That Gen-Probe's products do not and will not infringe any valid claims of '338 patent;

b. That the claims of the '338 patent are invalid; and

c. Of Gen-Probe's rights and obligations under the parties' License;

2. For a preliminary and permanent injunction enjoining and restraining defendant, its respective officers, agents, servants, employees and attorneys, and all persons acting in concert with them, and each of them:

a. From making any claims to any person or entity that Gen-Probe's products infringe the '338 patent;

b. From interfering with, or threatening to interfere with the manufacture, sale, license, or use of Gen-Probe's products by Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns, and others; and

c. From instituting or prosecuting any lawsuit or proceeding, placing in issue the right of Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns, and others to make, use or sell Gen-Probe's products;

3. For recovery of Gen-Probe's damages, as proven at time of trial, and restitution of any sums by which Vysis has been unjustly enriched;

4. For recovery of Gen-Probe's attorneys' fees and costs of suit incurred herein; and

5. For such other and further relief as the Court may deem just and proper.

Dated: January 25 1999

COOLEY GODWARD LLP
STEPHEN P. SWINTON (106398)
JAMES DONATO (146140)

By: Stephen P. Swinton

Attorneys for Plaintiff
Gen-Probe Incorporated